DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

OCT 28 2002

Richard S. Morey
Kleinfeld, Kaplan and Becker
1140 Nineteenth Street, N.W.
Washington, D.C. 20036-6606

Re: Docket No. 98N-0337
Comment No. LET14

Dear Mr. Morey,

This is in response to your letter dated July 26, 2002, coded LET14 under Docket No. 98N-0337 in FDA's Dockets Management Branch, regarding the Food and Drug Administration's (FDA) response to Becton Dickinson and Company's (Becton Dickinson) Application for Exemption (Docket No. 98N-0337/Comment No. ANS17). That application requested exemption from the labeling requirements for over-the-counter (OTC) drug products (21 CFR 201.66) for the company's BACTEC Blood Culture Procedural Tray. This product is a convenience kit containing OTC drug products, intended for use by healthcare professionals to collect and culture organisms from blood.

In its Application for Exemption dated July 6, 2001 (Comment No. APP17), Becton Dickinson stated that the BACTEC convenience kit should be exempt from the requirements in 21 CFR 201.66 because the product is intended for use solely by healthcare professionals. FDA denied the company's request in a letter (Comment No. ANS17) dated June 5, 2002, stating that although the convenience kit is intended for professional use only, the labeling requirements in 21 CFR 201.66 do not distinguish between OTC drug products marketed to consumers and those marketed to healthcare professionals. The letter further stated that, because the convenience kits are used daily by individuals with varying experience, these products should contain complete labeling to ensure safe and proper use.

You stated that other manufacturers of convenience kits and OTC drug products intended for professional use would agree with Becton Dickinson's conclusion that these products should be exempt from the labeling requirements in 21 CFR 201.66. You mentioned that there are other similar

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products that are labeled or could be labeled in such a manner that would require that these products must also meet the requirements in 21 CFR 201.66. You requested that the agency issue a guidance document to assist manufacturers who have considered the outer containers of OTC drug products intended for professional use only to be exempt from the requirements in 21 CFR 201.66, and wish to continue in that status. Specifically, you stated that it would be useful for the agency to issue an official statement of its position on the addition of text that might qualify products solely intended for professional use only to be exempt from some or all of the format requirements of 21 CFR 201.66(d). You suggested that this could include qualifying statements such as: (1) "For Hospital/Professional Use Only," (2) "Not For Retail Sale," and (3) "Not Labeled For Consumer Use," with the statement prominently displayed on the principal display panel of the product.

The agency has reviewed your request, and we have the following comments:

1. OTC drug products are generally recognized as safe and effective (GRAS/E) only under certain conditions, including specific labeling that contains active ingredients, indications, warnings, and directions for safe use. In fact, the agency has an ongoing rulemaking to establish GRAS/E conditions for OTC drug products such as healthcare personnel handwashes, surgical hand scrubs, and patient preoperative skin preparations. Although these and other OTC drug products are intended for use by various healthcare professionals in hospitals, clinics, or similar sites used by healthcare providers, the agency considers these products GRAS/E only when they include complete labeling. As Becton Dickinson was informed in the agency's June 5, 2002 letter, marketing of OTC drug products intended for professional use only does not preclude the need for labeling as required by 21 CFR 201.66.

2. In the absence of data, FDA would not consider an exemption from 21 CFR 201.66 for OTC drug products intended for professional use only based solely on the addition of certain qualifying statements in the labeling. The agency is unaware of data or information providing evidence that

granting such an exemption would not compromise the safety and effectiveness of these products.

3. Further, it is unclear whether you are requesting a categorical exemption for all OTC drug products intended for professional use only based on qualifying statements in the labeling and, if so, on what basis. The implications of such a request are broad in scope. We believe such an exemption could require a notice and comment rulemaking. We do not believe we have adequate basis to issue a guidance or equivalent document at this time. Your letter does not provide sufficient justification or basis for the agency to take either action.

If you have any questions, please contact Robert Sherman of my staff at 301-827-2222.

Sincerely yours,

Charles J. Ganley, M.D.

Charles J. Ganley, M.D.
Director
Division of OTC Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: 10/28/02

FROM: Director
Division of OTC Drug Products, HFD-560

SUBJECT: Material for Docket No. 98N-0337

TO: Dockets Management Branch, HFA-305

☒ The attached material should be placed on public display under the above referenced Docket No.

☒ This material should be cross-referenced to Comment No. LET 14

Charles J. Ganley, M.D.

Attachment